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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,889	09/18/2000	Gary J. Nabel	8642/91	6450
757	7590	08/26/2004	EXAMINER	
BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610			KELLY, ROBERT M	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary**Application No.**

09/663,889

Applicant(s)

NABEL ET AL.

Examiner

Robert M Kelly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17 and 19-36 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 17 and 19-36 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment and Request for Reconsideration under 37 CFR 1.111 filed 1 June 2004 have been entered.

Claims 17 and 19-36 remain pending and are currently considered.

Examiner Reassignment

The Examiner prosecuting this application has been changed. Any inquiries relating to the examination of the application should be directed to Examiner Robert M. Kelly. The phone numbers for Examiner Kelly and SPE Amy Nelson are provided at the end of this office action.

Priority

Applicant's claim of priority to U.S. Serial Nos. 08/533,942, 09/031,572, and 09/426,325, filed 9/26/95, 2/26/98, and 10/25/99, respectively, remain denied for reasons of record in the Official Action of 29 January 2004, pp. 2-4.

Response to Arguments

Applicant's arguments of 1 June 2004 have been fully considered but are not found persuasive.

Applicant argues that the specification describes a method of using a catheter for administration of a vector comprising a p21 gene, and that, therefore, the combination of such catheter and gene that affects that use is necessarily also described (Applicant's Response of 1 June 2004, p. 3, third paragraph).

This argument is not persuasive because, as stated in the Official Action of 29 January 2004, "The recited passages do not describe or suggest a combination of a gene encoding p21 and a catheter as a product. It appears that the instant claims are directed to a 'product' comprising a gene encoding p21 and a catheter rather than a method requiring the use of separate products including a gene encoding p21 and a catheter. It would appear that the Applicant is attempting to satisfy the written description requirement through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement." (pp. 3-4, paragraph bridging).

Applicant argues that the disclosures of the parent Applications are identical to that of the instant Application, and therefore, priority should also be given to the parent applications.

This argument is not persuasive for the same reasons as that given to the present application: as stated in the Official Action of 29 January 2004, "The recited passages do not describe or suggest a combination of a gene encoding p21 and a catheter as a product. It appears that the instant claims are directed to a 'product' comprising a gene encoding p21 and a catheter rather than a method requiring the use of separate products including a gene encoding p21 and a catheter. It would appear that the Applicant is attempting to satisfy the written description requirement through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement." (pp. 3-4, paragraph bridging).

Applicant argues that there has been no attempt to satisfy the written description through obviousness, but that this is not the case because the application, as well as its

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parents, disclose the method, and therefore must also teach the components and steps for practicing it.

This argument is not considered persuasive because, as stated in the Official Action of 29 January 2004, the passages do not describe or suggest a combination of a gene encoding p21 and a catheter as a product (pp. 3-4, paragraph bridging).

Moreover, to emphasize the point, Merriam Webster's Collegiate Dictionary (1997) 10th Ed., p. 228 provides a definition for "combination". The closest definition to that of Applicant's use of combination is that related to chemistry: "a: the act or process of combining; *esp* : that of uniting to form a chemical compound b: the quality or state of being combined." Such is not what Applicant appears to be claiming, which is a catheter containing a solution which comprises a p21-encoding nucleic acid and which does not meet the definition to known to an Artisan.

Therefore, Applicant's claims to priority remain denied.

Oath/Declaration

The requirement for a new oath/declaration is maintained for reasons of record in the Official Action of 29 January 2004, pp. 4-5, paragraphs bridging.

Response to Arguments

Applicant's arguments of 1 June 2004 have been fully considered but are not found persuasive.

Applicant argues that claims in a continuation application not claimed as part of the invention of a parent application does not prevent the continuation from receiving benefit of the filing date of the parent application (p. 2, first paragraph).

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Such argument is not persuasive because, as stated in the Official Action of 29 January 2004, the instant claims are not originally claimed **or** embraced in the statement of invention (p. 5, second paragraph).

Applicants argue that although the subject matter was not claimed originally, they are entitled to claim properly supported subject matter at any time during the pendency of the application (p. 2, last paragraph).

Such is not persuasive for the same reasons given above: as stated in the Official Action of 29 January 2004, the instant claims are not originally claimed **or** embraced in the statement of invention (p. 5, second paragraph).

Therefore, the requirement for a new oath/declaration is maintained.

Claim Rejections – 35 USC 112, first paragraph

Claims 17 and 19-36 remain rejected for reasons of record in the Official Action of 29 January 2004, for failing to comply with the written description requirement (pp. 5-7).

Response to Arguments

Applicant's arguments of 1 June 2004 have been fully considered but are not found persuasive.

Applicant argues that *ipsis verbis* recitation of claim terms is not required and that the disclosed method could not be practiced without the claimed combination (p. 5, first full paragraph).

Such is not considered persuasive for reasons of record. To wit, "The specification provides no implicit or explicit support for a combination comprising a catheter and a nucleic acid comprising a gene encoding p21 The specification has

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only provided for the use of a catheter and an expression vector comprising a gene encoding p21 in a treatment, but has not otherwise even contemplated a combination, as a product, comprising the same.” (Official Action of 29 January 2004, p. 6, first paragraph). Moreover, the Artisan would not have understood that the Applicant was in possession of the claimed combination at the time of invention because the Artisan would not have understood a combination to be a product of a catheter comprising a solution of a nucleic acid encoding p21 (e.g., Official Action of 29 January 2004, pp. 3-4, paragraph bridging).

Hence, the rejection of Claims 17 and 19-36 under 35 USC 112, first paragraph, as failing to comply with the written description requirement are maintained for reasons of record.

Claim Rejections – 35 USC 102

Claims 17 and 19-36 remain rejected for reasons of record under 35 USC 102(b) as being anticipated by Nabel, et al. (U.S. Patent No. 5,863,904).

Response to Arguments

Applicant’s arguments of 1 June 2004 have been fully considered but are not found persuasive.

Applicant argues that, because they have demonstrated priority, such priority overcomes this rejection (Applicant’s response of 1 June 2004, pp. 5-6, paragraphs bridging).

The argument is not persuasive because Applicants have not demonstrated priority (See pp. 2-4 of this Official Action).

Therefore, the rejection of Claims 17 and 19-36 stands for reasons of record under 35 USC 102(b) as being anticipated by Nabel, et al. (U.S. Patent No. 5,863,904).

Claim Rejections – 35 USC 102

Claims 17, 20-22, and 31 remain rejected under 35 USC 102(b) as being anticipated by Xiong, et al. (Nature, 1993, 366: 701-704), for reasons of record in the Official Action of 29 January 2004, p. 9.

Response to Arguments

Applicant's arguments of 1 June 2004 have been fully considered but are not found persuasive.

Applicant argues that the meaning of catheter has a well defined meaning to those of skill in the art and that such does not encompass pipette tips or eppendorf tubing, citing a dictionary reference "slender, flexible tube of metal, rubber, or plastic inserted into a body channel, such as a vein, to distend or maintain an opening to an internal cavity" (Applicant's response of 1 June 2004, pp. 6-7, paragraph bridging).

Such argument is not considered persuasive, for reasons of record in the prior Official Action of 29 January 2004, p. 9. To wit, at the times that the vector was present in tubing or pipette tip, such claims were anticipated. Applicant's definition recites an intended use of such catheter, but just as the catheter may be used to inject substances into a petri dish, or the rubber tubing or pipette tip may be used to inject material into a body cavity, the intended use of such catheter is not relevant to a product claim.

Moreover, whether a gene encoding p21 is present in a catheter, a petri dish, a syringe, or any other device, the gene encoding p21 is not materially different.

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Hence, Claims 17, 20-22, and 31 remain rejected under 35 USC 102(b) as being anticipated by Xiong, et al. (Nature, 1993, 366: 701-704), for reasons of record in the Official Action of 29 January 2004, p. 9.

Claim Rejections – 35 USC 103

Claims 17 and 19 remain rejected under 35 USC 103(a) as being unpatentable over Xiong taken with Nabel et al. (Science 1990, 249: 1285-88), for reasons of record in the Official Action of 29 January 2004, pp. 10-11.

Response to Arguments

Applicant's arguments of 1 June 2004 have been fully considered but are not found persuasive.

Applicant argues that Xiong fails as a primary reference, referring to the 102(b) rejection above (p. 7 of this Action), and Nabel does not make up for the deficiencies.

Applicant's argument is not persuasive because Xiong does not fail as a primary reference, as demonstrated on p. 7 of this Action.

Hence, Claims 17 and 19 remain rejected under 35 USC 103(a) as being unpatentable over Xiong taken with Nabel et al. (Science 1990, 249: 1285-88), for reasons of record in the Official Action of 29 January 2004, pp. 10-11.

CONCLUSION

No Claim is allowed. All Claims are rejected for reasons of record in the prior Official Actions.

Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER